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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/611,409 | 06/30/2003 | Steven M. Fischer | 10010632-3 | 1968 |

22878 7590 04/24/2007
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| EXAMINER |
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TUNG, JOYCE

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| ART UNIT | PAPER NUMBER |
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1637

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 04/24/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|-----------------|--------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/611,409 | FISCHER, STEVEN M. | |
| | Examiner | Art Unit | |
| | Joyce Tung | 1637 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-34 and 42-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The applicant's response filed 2/13/07 to the Office action has been entered. Claims 21-34 and 42-43.

1. The rejection of claim 43 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn because of the amendment.
2. The rejection of claim 22-24 and 43 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn because of the amendment.
3. Claims 21-31, 33-34 and 42-43 remain rejected under 35 U.S.C. 102(b) as being anticipated by Schmidt et al. (WO 99/02728, issued January 21, 1999).

Schmidt et al. disclose that a series of DNA fragments is provided by contacting a template in the presence of DNA polymerase with a mixture of nucleotides sufficient for hybridizing to the template for forming a second strand of DNA complementary to the template. The mixture comprises a set of four probes containing all four nucleotides for hybridizing to the template in which the nucleotide of each probe comprises a modified nucleotide, which is capable of polymerizing to the second strand of DNA, but blocked to prevent further polymerization and which is cleavably attached to the mass label. The mass label is identified by mass spectrometry for the modified nucleotide (See pg. 3, paragraph 5 and pg. 4, paragraph 1). The mass label is corresponding to a modified nucleotide so that the nucleotide present in the target template may be deduced (See pg. Paragraph 4). The cleavage is done by photolysis or chemical cleavage (See pg. 12, paragraph 2, pg. 13, paragraph 2, pg. 46, paragraph 4). Ligating is also used to produce extended products (See pg. 12, paragraph 1 and 3). The cleavable tag is a

Art Unit: 1637

3' cleavable tag (See pg. 46, paragraph 5, fig. 4a and fig. 13) in which the cleavable tag is attached to the 3' end.

Schmidt et al. do not explicitly disclose the cleavable tag is an acid or base cleavable tag as recited in claims 29 and 30. However, Schmidt et al. disclose that the cleavage is done by photolysis or chemical cleavage (See pg. 12, paragraph 2, pg. 13, paragraph 2, pg. 46, paragraph 4). This teaching is inherent that the cleavable tag is an acid or base cleavable tag. Thus, the teachings of Schmidt et al. anticipate the limitations of Schmidt et al.

The response argues that Schmidt et al. do not disclose a method of determining a nucleic acid sequence that results in the production of cleaved tag and an extension product wherein the extension product includes the at least one complementary nucleotide that is hybridized to the template nucleic acid sequence, while Schmidt et al. disclose that a population of tagged extension products is dissociated from template nucleic acids, then the individual extension products are separated prior to cleavage and detection of the tag (See pg. 2, last paragraph to pg. 3). However, based upon the disclosure of the specification, prior to cleavage of the tag from the extended base on the DNA template, the excess, unincorporated dNTPs are preferably removed from the extension reaction, the tags may be removed by any of a variety of washing or rinsing procedures that separate the excess, unincorporated dNTPs from the extended DNA template, and in one preferred embodiment, the extension reaction is contained within a chamber that has an attached filtration membrane, e.g., an ultrafiltration membrane, that allows small molecules such as water, salts, and cdNTPs to pass through, while retaining large molecules such as ssDNA (See pg. 3 [0018], [0030], [0048] of US 2004/0033522). So there is some type of separation of the extension products from the extension reaction before the cleavage of the tag. In addition, the

Art Unit: 1637

phrase "away from said extension product" is interpreted as that the cleaved tag is separated from the extension product⁹. Based upon the analysis above, the rejection is maintained.

4. Claim 32 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt et al. (WO 99/02728, issued January 21, 1999) as applied to claims 21-31, and 33-34 in view of Cheeseman et al. (5,302,509, issued Apr. 12, 1994).

The teachings of Schmidt et al. are set forth in section 3 above. Schmidt et al do not disclose that the cleavable tag is a fluorescent tag.

Cheeseman et al. disclose a method for determining the sequence of nucleotides on a single strand DNA in which the cleavable tag is a fluorescent tag (See column 2, lines 57-59 and column 6, lines 11-13).

One of ordinary skill in the art would have been motivated to apply a fluorescent tag for the cleavable tag because Cheeseman et al. apply the fluorescent for the cleavable tag for nucleic acid sequencing. It would have been prima facie obvious to apply a fluorescent tag for the cleavable tag for nucleic acid sequencing.

The response does not have specific argument regarding the rejection. With the same reasons as set forth in section 3 above, the rejection is maintained.

NEW GROUND REJECTION IS NECESSITATED BY THE AMENDMENT

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1637

6. Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added limitation wherein said extension product is not separated from said "sample" has no support in the specification because in the specification, it discloses that prior to cleavage of the tag from the extended base on the DNA template, the excess, unincorporated cdNTPs are preferably removed from the extension reaction, the tags may be removed by any of a variety of washing or rinsing procedures that separate the excess, unincorporated dNTPs from the extended DNA template, and in one preferred embodiment, the extension reaction is contained within a chamber that has an attached filtration membrane, e.g., an ultrafiltration membrane, that allows small molecules such as water, salts, and cdNTPs to pass through, while retaining large molecules such as ssDNA (See pg. 3 [0018], [0030], [0048]. [0049] of US 2004/0033522). By doing so, the extension products are separated from the sample. Thus, the new limitation has no support in the specification. It constitutes new matter.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

Art Unit: 1637

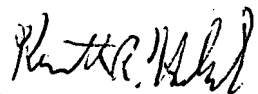
will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joyce Tung
April 18, 2007


KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER
4/18/07